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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/163,289	09/29/1998	HARRY C. DIETZ	JHU1400-1	9819

7590 12/24/2003

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EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed September 10, 2003 has been considered. Rejections and/or objections not reiterated from the previous office action mailed May 6, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments***

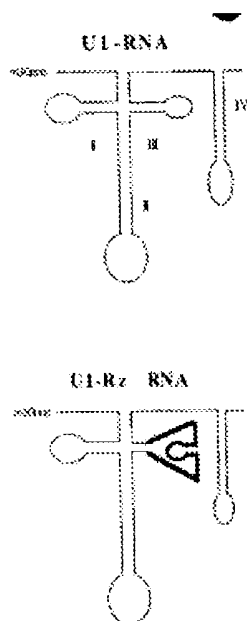
Claims 1-13 rejected under 35 U.S.C. 102(a) as being anticipated by Michienzi et al., and is repeated for the same reasons of record as cited in the Office action mailed May 6, 2003.

Applicants have traversed the instant rejection by asserting that Michienzi et al. do not teach all the elements of the claimed invention. Applicants assert that "Michienzi does not teach a nucleic acid construct with the 5' to 3' orientation of the claimed construct, nor a construct containing an antisense, where the antisense suppresses gene expression, nor a construct where the stem loop structures flank the antisense and the antisense is not within the 3' or 5' stem loop structures."

Claim 1 recites "a nucleic acid construct for suppressing gene expression comprising in 5' to 3' operable orientation: a 5' stem loop structure; an antisense nucleic acid, and a 3' stem loop structure, wherein the antisense nucleic acid suppresses gene expression and is flanked by the stem loop structures and with the proviso that the antisense nucleic acid is not within the 5' or 3' stem loop structures." Applicants contention that Michienzi does not teach all the claim

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limitations is based on the assertion that because Michienzi teaches a ribozyme (comprising a catalytic core flanked by antisense sequences) that itself may comprise a stem loop structure as seen in figure 1 of Michienzi, reproduced below.



Applicants apparently contend that because the ribozyme (and by extension the antisense construct linked to the ribozyme) cannot read on the instant claim 1, because Michienzi does not meet applicants' proviso that "the antisense nucleic acid is not within the 5' or 3' stem loop structures". However, Michienzi identifies four stem loop regions in their construct, labeled I-IV as seen in the figure labeled "U1-RNA". Applicants proviso specifies only that their construct may not be in the 5' or 3' stem loop structure. Clearly, the ribozyme/antisense construct of Michienzi, depicted in bold within the U1-Rz RNA construct, is a part of stem-loop structure III, and not a part of either the 5' structure (i.e. stem-loop I) or the 3' stem-loop structure (i.e. stem-loop IV). Particularly in light of the fact that applicants employ the open (comprising) claim

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language in describing the nucleic acid constructs, applicants contention that said proviso frees the claim from the prior art is not convincing.

Applicants also allege that Michienzi et al. teach away from antisense constructs that contain 5' and 3' stem-loop structures because "Michienzi specifically states that derivatives with a C to G substitution were utilized to control for the antisense effect of ribozymes." Applicants apparently suggest that since Michienzi attempted to control for antisense effects by introducing an antisense mismatch, that one of skill would not be motivated to use such constructs containing antisense sequences. This is not convincing, because this does not rise to the level of a teaching away. Michienzi et al. were simply trying to establish the effectiveness of ribozyme cleavage of the target, and wanted to eliminate competing variables, such as any cleavage which may be induced by the antisense aspect of the ribozyme. However, even if Michienzi et al. does teach away, such an assertion is irrelevant in the analysis of anticipation.

Applicants are directed to the discussion of anticipation of M.P.E.P. § 2123:

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

Since this rejection is maintained under 35 U.S.C. § 102(a), and not under 35 U.S.C. § 103(a) where such a teaching away might be considered, arguments pertaining thereto are not considered relevant.

Regarding applicants arguments that the constructs of the instant invention are not modified, and that the compound of Michienzi is modified, it is noted that this feature upon

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which applicant relies (i.e., modified vs. unmodified) are not recited in the rejected claims.

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus, since applicants claims do not recite the term modified or unmodified, applicants arguments drawn thereto are not considered relevant to the novelty of the claims as written.

Furthermore at the bottom of page 8 of applicants response applicants state that "The claimed invention does not allow for the presence of the antisense within the stem loop."

Applicants are reminded that the claim language is actually broader, and does not allow for antisense *only within the 5' or 3' stem loops*. Michienzi does not teach an antisense within the 5' or the 3' stem-loops, but rather teaches the antisense within a stem loop that is internal to either the 5' or the 3' stem loop.

Finally applicants arguments assert that there are three requirements of claim 1 that are not met by Michienzi. First, that the antisense nucleic acid be flanked by the stem loop structures. However, as can be seen in the figure depicting U1-Rz RNA, the antisense/ribozyme element is flanked by the stem loop structure on the 3' end, and by stem loop structures I and II on the 5' end. Therefore, this element is considered to be met. Second, applicants contend that the antisense nucleic acid suppress gene expression. Figure 2 clearly shows that the antisense/ribozyme construct cleaves the 166 assay product in a time dependent manner. Thus, this element is considered to be met. Third, applicants contend that the antisense nucleic acid not be within either the 3' or the 5' stem loop structures. This issue has been addressed in some detail above, and is considered to be met by Michienzi. Therefore, Michienzi is considered to teach all the elements of, and thus anticipates, applicants claimed invention.

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The amended sequence listings filed January 30, 2001 and May 8, 2001 are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NOS: 3, 4, and 5.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

**This is a new matter rejection.**

Claim 16 is drawn to SEQ ID NO: 3.

Applicants' instant application claims priority via divisional status to U.S. application serial number 08/742,943. This parent application does not contain SEQ ID NO: 3. Furthermore,

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in reviewing the instant file history of sequence submissions, SEQ ID NO: 3 was first submitted on January 30, 2001, well beyond the instant filing date of September 29, 1998. Accordingly, claim 16 claiming SEQ ID NO: 3 is rejected for containing new matter.

*Allowable Subject Matter*

Claim 15 is allowed for reasons of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

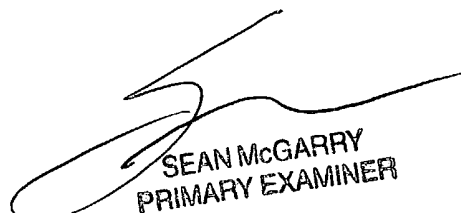
Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD

  
SEAN MCGARRY  
PRIMARY EXAMINER  
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